K013302

DEC 17 2001

XIII. SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
DURAPRENE STERILE SYNTHETIC POWDER-FREE SURGICAL GLOVES

Manufacturer:	Allegiance Healthcare Sdn. Bhd. Plot 87, Kampung Jawa 11900 Bayan Lepas Penang, West Malaysia
Regulatory Affairs Contact:	Erica Sethi Allegiance Healthcare Corporation 1500 Waukegan Road, MP-WM McGaw Park, IL 60085
Telephone:	(847) 785-3337
Date Summary Prepared:	9/17/01
Product Trade Name:	Duraprene Sterile Synthetic Powder-Free Surgical Gloves
Common Name:	Surgical Glove
Classification:	Glove, Surgeon's
Predicate Devices:	Duraprene Sterile Synthetic Powder-Free Surgical Gloves
Description: formulated	Duraprene Sterile Synthetic Powder-Free Surgical gloves are using neoprene and are coated with a nitrile coating. These are offered powder-free and sterile.
Intended Use:	Duraprene Sterile Synthetic Powder-Free Surgical Gloves are intended for use in environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility. They are intended to be worn by operating room personnel to protect a surgical wound from contamination.

K013302

Substantial Equivalence:	Duraprene Sterile Synthetic Powder-Free Surgical Gloves are substantially equivalent to currently marketed Duraprene Sterile Powder-Free Surgical Gloves in that they provide the following characteristics: - same intended use - same sizes, configuration, packaging - both made of neoprene

Summary of Testing:

Test	Result
Intracutaneous Reactivity	Gloves show no reactivity.
Guinea Pig Maximization	Gloves do not display any potential for irritation.
Barrier Defects	Gloves exceed requirements per 21 CFR §800.20 and ASTM D3577-00, AQL = 1.5.
Standard	ASTM D 3577-00
Data/Test Method	Gloves meet powder level requirements for "Powder Free" designation using ASTM Standard D6124-00-Standard test method for residual powder on medical gloves. Results generated values below 2 mg of residual powder per glove.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 7 2001

C/O Ms. Erica Sethi
Regulatory Affairs Manager
Allegiance Healthcare Corporation
Quality & Regulatory Affairs Division
1500 Waukegan Road, Bldg. WM
McGraw Park, Illinois 60085

Re: K013302
Trade/Device Name: Duraprene Sterile Synthetic Powder-Free Surgical Gloves with Tested for use with Chemotherapy Drugs Labeling Claim
Regulation Number: 878.4460
Regulation Name: Surgeon's Gloves
Regulatory Class: I
Product Code: KGO
Dated: September 17, 2001
Received: October 3, 2001

Dear Ms. Sethi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2460

Applicant: Allegiance Healthcare Corporation

510(k) Number: K013302

Device Name: DURAPRENE STERILE SYNTHETIC POWDER-FREE SURGICAL GLOVES WITH TESTED FOR USE WITH CHEMOTHERAPY DRUGS LABELING CLAIM.

Indications For Use: These gloves are intended for use in environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive as well as non-invasive medical procedures requiring sterility. They are intended to be worn by operating room personnel to protect a surgical wound from contamination.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013302